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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,672	10/02/2000	Jean-Christophe Francis Audonnet	454313-3160	3424

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FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
NGUYEN, DAVE TRONG	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/677,672	AUDONNET ET AL.	
	Examiner	Art Unit	
	Dave T Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The specification has been amended, and Claim 19 has been added by the amendment dated January 23, 2004.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The priority French application has been entered together with its translated copy. As such, the rejection over Ross has been withdrawn by the examiner.

The rejection over the Chavez reference has been withdrawn by the examiner because of applicant 's response on page 8 of the response.

Claims 1-19 are rejected under 35 USC 103(a) as being unpatentable over any of Davis (US 2002/0164341 A1) taken with any of Miles Inc. (EP 0 532 833 A1), Lowell, Chavez, Gicquel (US 2001, 0024653 A1) or Wasmoen (US 5,989,562).

Davis teaches a DNA vaccine comprising a polymer composed adjuvant (par. 0008, page 1, par. 0070-71, page 8, entire page 14. The antigen encoded by the DNA vaccine can be a pathogen antigen obtained from equine rhinopneumoonia virus, equine influenza virus, Eastern encephalitis virus, Western encephalitis virus, Venezuenlan encephalitis, rabies virus and FIV.

Davis do not teach an incorporation of a sugar based polymer such as EMA or Carbopol® as adjuvants in the DNA vaccine composition so as to enhance its vaccinated effect.

However, at the time the invention was made, Miles Inc. teaches a combination vaccine comprising an adjuvant preferably a Carbopol acrylic-based adjuvant is effective for use in protecting horse against EHV (entire document, abstract, page 4, lines 18-22).

In addition, Lowell teaches that polymeric adjuvant including those of polyacrylic acid and/or polymethacrylic acid (e.g., CARBOPOL, CARBOMER), poly(methylvinul ether/maleic anhydride) copolymer, and their mixtures and copolymers in a final concentration of 0.01-0.5% (w/v) are effective for use conferring bioadhesive

properties, *e.g.,* enhances the delivery and attachment of antigens on or through the target mucous surface conferring mucosal immunity (page 15).

Likewise and even in the art of DNA vaccine, the concept of utilizing such adjuvants are well known in the prior art, *e.g.,* see Wasmoen, column 4, Chavez, column 4, Gicquel, page 5.

The art of employing an origin of replication, a promoter, and a termination sequence is conventional in the prior art of constructing plasmid DNA, and thus, is obvious to a person of ordinary skill in the art, particularly in view of the totality of the prior art of record.

With respect to the main thrust of the claimed invention, one of ordinary skill in the art would have been motivated to employ any commercially available polymer-based adjuvant such as EMA in DNA vaccine composition taught by the combined cited references. One of ordinary skill in the art of polymer based adjuvant would have been motivated to employ EMA rather than just making one on the basis of the teaching of the combined cited references because of the ease and convenience of obtaining the adjuvants from the prior art and because of the well-known fact obtained from the totality of the prior art, which teaches that EMA and CARBOPOL are effective adjuvants for use in any vaccination method including DNA vaccination methods, see Wasmoen.

Thus, the claimed invention as a whole was *prima facie* obvious.

Applicant's response (pages 9-11) has been considered by the examiner but is not found persuasive in view of the reasons set forth above. Applicant mainly argues that the

concept of employing the claimed EMA and CARBOPOL as adjuvants in DNA vaccine composition is now taught any where but applicant's disclosure, and that the use of teaching from protein vaccine wherein EMA or CARBOPOL is employed cannot be the basis for the rejection. The argument is not found persuasive because Davis clearly taught that a polymer based adjuvant can be used in combination with a DNA vaccine, and to the extent that the secondary references not only teach that EMA or CARPOPOL can be used to increase bioadhesive activities of an antigen present *in vivo,* but also teach that the polymers can be used to enhance the vaccination effect of a recombinant expression vector such as mycobacteria, which acts similarly to plasmid expression vectors, one of ordinary skill in the art would have been motivated to employ a polymer based adjuvant as embraced by the claims in order to enhance the bioadhesive activities of an expressed antigen present in vivo to a mucosa, or to increase the adjuvant property of a polymer in the DNA vaccination method of Davis. As such, applicant's citations of *In re Dow, In re Laskowski, In re Fine, In re Fritch* are not found persuasive.

Applicant's submission of the enclosed graphs has been considered but is not sufficient to remove the prior art rejections. While the graphs may be found convincing to remove the prior art rejection with respect to the use of a carbomer as recited in claim 14, the enclosed graphs were not submitted in a form of a proper Declaration. As such, the enclosed graphs are not sufficient as factual evidence to remove the prior art rejection of record. Note that an unexpected property of a Carpopol, if found, may not be sufficient to be commensurate in scope with that of the presently pending claims.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(571-272-0731)**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson* may be reached at **571-272-0184.**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Trong Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER